

EXHIBIT 1

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<p>1 a whole variety of other data backing that up.</p> <p>2 Q. Are there any randomized controlled</p> <p>3 studies for that proposition?</p> <p>4 A. I believe there are.</p> <p>5 Q. All right. Talking about NSAIDs, are</p> <p>6 there any randomized controlled studies</p> <p>7 establishing that NSAIDs cause that picture?</p> <p>8 A. I don't know if that would have been</p> <p>9 done for NSAIDs, because it's such a broad</p> <p>10 class, and it's been around before there were</p> <p>11 regulations. Again, there's animal data and</p> <p>12 mechanistic data that make it clear that that's</p> <p>13 true.</p> <p>14 Q. Do you hold the opinion to a</p> <p>15 reasonable degree of medical certainty that</p> <p>16 NSAIDs cause in some patients villous atrophy,</p> <p>17 severe diarrhea, dehydration, weight loss, that</p> <p>18 picture?</p> <p>19 A. I think they can.</p> <p>20 Q. And just to be clear, is there any</p> <p>21 randomized controlled study you're pointing to</p> <p>22 for that proposition?</p> <p>23 A. No.</p> <p>24 Q. Is there any controlled study you're</p>	<p>1 person's weekend.</p> <p>2 A. I couldn't put a number on it. I'd</p> <p>3 say at least 15 years, perhaps more. I'm sure</p> <p>4 it's more.</p> <p>5 Q. With regard to NSAIDs, how long has</p> <p>6 that been known?</p> <p>7 A. Much more than that.</p> <p>8 Q. How about with mycophenolate?</p> <p>9 A. I think that's a newer drug, so I</p> <p>10 think it's less, but I would probably say at</p> <p>11 least ten years.</p> <p>12 Q. For clinical physicians who are</p> <p>13 actually treating patients who have the clinical</p> <p>14 syndrome that's been identified in the</p> <p>15 literature as olmesartan enteropathy, in order</p> <p>16 to treat their patients, do they need any more</p> <p>17 studies than what's out there, or is there</p> <p>18 sufficient information for them to know what</p> <p>19 this entity is as described, and to use that</p> <p>20 information to treat their patients?</p> <p>21 A. So first, I think it's been referred</p> <p>22 to mostly as olmesartan-associated enteropathy,</p> <p>23 not olmesartan enteropathy.</p> <p>24 Second, I think they have enough</p>
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<p>1 pointing to for that proposition where the</p> <p>2 patients were not randomized, but where there</p> <p>3 was a controlled study studying that issue?</p> <p>4 A. Individual case controls, I'm not</p> <p>5 aware of one.</p> <p>6 Q. Mycophenolate, do you hold the opinion</p> <p>7 to a reasonable degree of medical certainty that</p> <p>8 that can cause villous atrophy, severe diarrhea,</p> <p>9 dehydration, weight loss?</p> <p>10 A. Yes.</p> <p>11 Q. Are there any randomized controlled</p> <p>12 studies you're relying on for that opinion?</p> <p>13 A. I think that did come out in</p> <p>14 randomized clinical trials of mycophenolate.</p> <p>15 Q. Anything you can point to while you're</p> <p>16 sitting here, or are you just generally</p> <p>17 recalling that there's such a study?</p> <p>18 A. Not off the top of my head, no.</p> <p>19 Q. How long has methotrexate been known</p> <p>20 to cause the clinical picture you described,</p> <p>21 that I asked you about, how long has that been</p> <p>22 known?</p> <p>23 A. A pretty long time, I think.</p> <p>24 Q. One person's long time is another</p>	<p>1 information to be aware of it as a possible</p> <p>2 entity, and if their patient -- and to do a</p> <p>3 therapeutic trial by withdrawing the medication.</p> <p>4 If their patient does well, then they shouldn't</p> <p>5 put the patient back on olmesartan because there</p> <p>6 are plenty of alternatives, and they don't need</p> <p>7 more information for patient management.</p> <p>8 Q. So the state of the scientific</p> <p>9 literature is sufficient to provide the</p> <p>10 physicians who actually have to treat patients</p> <p>11 in this area with the information they need to</p> <p>12 treat the patients, fair statement?</p> <p>13 A. Fair statement.</p> <p>14 Q. Okay. Doctor, unless Mr. Parker</p> <p>15 reminds me of things I forgot to ask you, or</p> <p>16 asks any really, really insightful questions, I</p> <p>17 will probably not ask you more questions. But</p> <p>18 if he does, I will probably follow up. So his</p> <p>19 turn.</p> <p>20 THE VIDEOGRAPHER: If we could just go</p> <p>21 off the record for a moment, please.</p> <p>22 Going off the record. The time is</p> <p>23 4:42.</p> <p>24 (Whereupon, a recess was taken.)</p>

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<p style="text-align: right;">Page 302</p> <p>1 THE VIDEOGRAPHER: Back on the record.</p> <p>2 The time is 4:45.</p> <p>3 EXAMINATION</p> <p>4 BY MR. PARKER:</p> <p>5 Q. Okay. Dr. Turner, I want to follow up</p> <p>6 on a few areas that Mr. Slater has questioned</p> <p>7 you about in some instances a number of times</p> <p>8 today.</p> <p>9 Several hours ago Mr. Slater was</p> <p>10 asking you about a number of hypothetical cases</p> <p>11 of a patient who either had this or didn't have</p> <p>12 that, and went off olmesartan, had resolution of</p> <p>13 some symptoms, and you were asked essentially do</p> <p>14 you know what the reason would have been other</p> <p>15 than olmesartan, words to that effect.</p> <p>16 Do you recall that series of</p> <p>17 questions?</p> <p>18 A. Yes, I do.</p> <p>19 Q. Doctor, are you familiar with the</p> <p>20 medical term idiopathic enteropathy and</p> <p>21 unclassified sprue?</p> <p>22 A. Yes.</p> <p>23 Q. Can you explain to the jury what those</p> <p>24 terms are?</p>	<p style="text-align: right;">Page 304</p> <p>1 villous atrophy cases, that's one of the top</p> <p>2 three diagnoses.</p> <p>3 Q. So -- never mind. Let me rephrase and</p> <p>4 go on.</p> <p>5 Doctor, you were asked by Mr. Slater</p> <p>6 about whether rechallenge was, I think his word</p> <p>7 was strong evidence of causation. Do you recall</p> <p>8 that series of questioning early this morning?</p> <p>9 A. Yes.</p> <p>10 Q. And in response to a number of his</p> <p>11 hypotheticals, you responded that it was an</p> <p>12 uncontrolled rechallenge.</p> <p>13 Do you recall that?</p> <p>14 A. Yes.</p> <p>15 MR. SLATER: Objection.</p> <p>16 BY MR. PARKER:</p> <p>17 Q. Can you share with the jury what, if</p> <p>18 any, importance there is on the question of</p> <p>19 causation if a rechallenge is controlled versus</p> <p>20 uncontrolled?</p> <p>21 A. Sure. A rechallenge essentially</p> <p>22 involves taking a patient who has recovered from</p> <p>23 whatever their illness is, in this case it's one</p> <p>24 of these patients who seems to do better after</p>
<p style="text-align: right;">Page 303</p> <p>1 A. Yes, it's essentially a sprue, which</p> <p>2 is a vague term in and of itself, but so a</p> <p>3 malabsorptive disease, an enteropathy associated</p> <p>4 with histopathology like that of celiac disease,</p> <p>5 like that of what's been associated -- reported</p> <p>6 in association with olmesartan, but that no</p> <p>7 specific cause has been identified, those</p> <p>8 patients usually respond to steroids, and they</p> <p>9 can remit spontaneously.</p> <p>10 Q. What does it mean, just so we're all</p> <p>11 clear, what does it mean to remit spontaneously?</p> <p>12 A. It means that you don't do any known</p> <p>13 intervention, and their condition improves.</p> <p>14 Q. And if I'm understanding correctly,</p> <p>15 there are patients for whom one -- not one, but</p> <p>16 physicians can't find a readily known</p> <p>17 explanation for their condition, and they</p> <p>18 receive a diagnosis of idiopathic enteropathy</p> <p>19 and/or unclassified sprue?</p> <p>20 A. Yes. When you start looking at --</p> <p>21 MR. SLATER: Objection.</p> <p>22 BY MR. PARKER:</p> <p>23 Q. You can go ahead.</p> <p>24 A. When you start looking at seronegative</p>	<p style="text-align: right;">Page 305</p> <p>1 stopping olmesartan, and then giving them</p> <p>2 olmesartan and asking whether they manifest the</p> <p>3 disease again, and I'll put that in quotes.</p> <p>4 The issues with doing it just in that</p> <p>5 way, which is more or less the way it's been</p> <p>6 done, except usually the readministration has</p> <p>7 not been intentional, the issue with doing it</p> <p>8 just in that way is that you don't know what</p> <p>9 else is going on, you haven't controlled for</p> <p>10 other variables, which there may be many. Most</p> <p>11 of these patients have been identified when</p> <p>12 they're reasonably ill.</p> <p>13 The second issue, and I think this is</p> <p>14 really a big one, is the placebo effect. So we</p> <p>15 know that in trials, in clinical trials,</p> <p>16 patients receiving placebo often improve. And</p> <p>17 so if you really want to ask is this a cause or</p> <p>18 effect, so in this case we're talking about</p> <p>19 rechallenge, you don't want to ask if I give</p> <p>20 this patient placebo does their disease recur,</p> <p>21 and to my knowledge, that hasn't been done. And</p> <p>22 I think even to prove causality in an individual</p> <p>23 case, you need data from that patient showing</p> <p>24 that you've done a randomized trial.</p>

<p style="text-align: right;">Page 306</p> <p>1 Q. And that's what I wanted to clarify. 2 You made reference a number of times in today's 3 deposition when talking about an individual to a 4 randomized controlled trial. 5 In the context of an individual, can 6 you explain to the jury what you mean when you 7 say "randomized"? 8 A. Sure. I think the expectation from, I 9 think, any clinical researcher would be that it 10 would be a double-blinded study, so the 11 physician giving the medicine and the patient 12 don't know if they're getting the medicine or 13 the placebo. You take the patient when they're 14 well. You give them either medicine or placebo. 15 You record their response over several weeks, 16 since it seems that this recurs pretty quickly 17 if we're going to conclude that those other 18 rechallenges are accurate and mean what the -- I 19 guess what Mr. Slater is taking them to mean. 20 If we're going to assume that that's 21 true, then you would expect to see a relapse of 22 symptoms within days to weeks. So put them on 23 that. Then allow for a washout period where if 24 they got sick they feel completely better, if</p>	<p style="text-align: right;">Page 308</p> <p>1 Q. Doctor, for the better part of 2 20 years before the auto antibodies were 3 identified that are specific to celiac disease, 4 was rechallenge the standard of care for 5 diagnosing that condition? 6 A. Yes, it was. 7 MR. SLATER: Objection. 8 BY MR. PARKER: 9 Q. Doctor, is there anything that you've 10 seen in the literature regarding the severity of 11 the symptoms in what's reported to be 12 olmesartan-associated enteropathy that would 13 suggest that if you really did want to find 14 cause that you couldn't do a rechallenge in the 15 way that you've described? 16 A. You certainly wouldn't do it at the 17 trough of their disease when they're at their 18 sickest. But if the reports that say they 19 recover completely, gain back their weight, and 20 don't have malabsorption anymore are true, I 21 don't see any reason why a short-term 22 rechallenge in the manner that I just described, 23 a randomized controlled trial, I don't see any 24 reason that couldn't be done.</p>
<p style="text-align: right;">Page 307</p> <p>1 they didn't get sick you still give them the 2 equivalent washout period, and now give them the 3 other pill. 4 So one case it's placebo, one case it 5 would be olmesartan. Neither the physician 6 prescribing and taking data from the patient 7 knows which one they received, the patient 8 doesn't know which one they received, then 9 you've eliminated placebo effect, and I think it 10 becomes very clear in that patient. 11 Q. Doctor, there was reference, 12 Mr. Slater showed you -- let me grab these for a 13 second -- in a number of papers or a handful of 14 papers where the investigator said, well, we 15 opted not to rechallenge because of the severity 16 of the symptoms, or words to that effect. 17 Do you recall that? 18 A. Yes, I do. 19 Q. Doctor, is celiac disease in some 20 people a very serious disorder? 21 A. Absolutely. 22 Q. Producing very serious, if not 23 life-threatening, symptoms in some people? 24 A. Absolutely.</p>	<p style="text-align: right;">Page 309</p> <p>1 Q. And for many years, what did the 2 standard of care require in terms of rechallenge 3 for diagnosing celiac disease? 4 A. For diagnosis of celiac disease, it 5 required rechallenge with gluten. I think 6 that's really the key difference here, if I can 7 opine for a second. 8 Q. Sure. 9 A. So in the case of celiac disease, 10 especially at that time in history, a 11 gluten-free diet was a huge difficulty. It's so 12 much easier today because it's become a popular 13 thing, and with the increasing presence of 14 celiac disease and gluten-sensitive patients who 15 don't have celiac disease, gluten-free diets are 16 everywhere, gluten-free foods are everywhere. 17 It's much easier. In those days, it was really, 18 really hard to do a gluten-free diet, so you 19 wanted to be sure. 20 In the case here of olmesartan, the 21 treatment is really easy. So if you're wrong 22 and it wasn't olmesartan, it really didn't hurt 23 anybody. There's no cost. And I think that's 24 why if you're managing an individual patient,</p>

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<p>1 you wouldn't say, let's do a proper rechallenge. 2 I think that's reasonable. Because if you're 3 managing the patient, they're doing better, why 4 would you do that? 5 Versus celiac disease, before you 6 would tell them, here, have this life-changing 7 event where you do a gluten-free diet, you want 8 to be sure. You don't want to tell them go on 9 this really difficult diet where you can't eat 10 at restaurants for the rest of your life unless 11 you're sure that's what's making them sick. 12 So in that context, it was 13 well-recognized in those days that a therapeutic 14 trial of a gluten-free diet, it's still 15 recognized today, response to gluten-free diet 16 is not evidence of celiac disease. That's not 17 sufficient. So I think that's the big 18 difference here. 19 Q. Okay. Let's turn to Exhibit 20 Number 10, which is the paper Mr. Slater 21 discussed with you, the Marietta paper. 22 A. Yes. 23 Q. And I think he referred you to 24 Page 217 of this paper.</p>	<p>1 Q. These authors -- 2 MR. SLATER: I don't see what you're 3 -- oh, that's the second page, okay. Actually I 4 don't really know what you're looking at, to 5 tell you the truth. Above "Treatment"? 6 MR. PARKER: Right above treatment, 7 I'll read into the record what you read to him. 8 BY MR. PARKER: 9 Q. "The Mini-Sentinel study on olmesartan 10 and celiac disease by the FDA found 10 of 23 11 patients had a positive rechallenge." I believe 12 that's what was read to you. 13 A. Yes. 14 MR. PARKER: All right. Are you with 15 me, Adam? 16 MR. SLATER: I remember reading it. 17 THE WITNESS: You're looking at the 18 wrong Marietta. 19 MR. PARKER: I think you're looking at 20 the wrong paper, Adam. This is the -- 21 MR. SLATER: Are you talking about -- 22 THE WITNESS: The one in Digestive 23 Diseases. 24 MR. PARKER: Your Exhibit 10.</p>
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<p>1 A. This copy just has Pages 1 through 5, 2 6, doesn't have the page numbers on it. 3 Q. I don't think you're looking at the 4 right paper. This is the Drug-Induced -- 5 A. Oh, that, wrong Marietta paper. I'm 6 sorry. 7 Q. Exhibit 10. 8 A. I'm sorry. 9 MR. SLATER: Come on, guys, get on the 10 same page, let's go. 11 MR. PARKER: We're trying. 12 A. Yes. 13 BY MR. PARKER: 14 Q. All right. Mr. Slater directed you to 15 Page 217, so let's go there. 16 MR. SLATER: I don't have numbering of 17 217, you've just got to tell me which page that 18 is. 19 THE WITNESS: It's the third page of 20 the article. 21 MR. SLATER: Third page? 22 MR. PARKER: Yes. Right above 23 "Treatment." 24 BY MR. PARKER:</p>	<p>1 MR. SLATER: You've got to give me a 2 second. 3 MR. PARKER: Sure. 4 MR. SLATER: It's the Drug-Induced 5 Enteropathy article, right? 6 MR. PARKER: Correct. 7 MR. SLATER: I don't know where it is. 8 Just continue. 9 BY MR. PARKER: 10 Q. Okay. Let's go back and clean up the 11 record. 12 Doctor, we're looking at Exhibit 10, 13 the article entitled "Drug-Induced Enteropathy," 14 the lead author is Marietta, correct? 15 A. Correct. 16 Q. You were referred by Mr. Slater to 17 Page 217, the statement that I just previously 18 read to you about the Mini-Sentinel? 19 A. Yes. 20 Q. Is there any reference that these 21 authors give for that statement? 22 A. No. 23 Q. Doctor, you have the Mini-Sentinel 24 study that I think you were glancing through</p>

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<p style="text-align: right;">Page 314</p> <p>1 initially, do you not?</p> <p>2 A. Yes.</p> <p>3 Q. Doctor, could you look at that and</p> <p>4 tell us whether there is any information in that</p> <p>5 study on individual cases, and any --</p> <p>6 specifically anything about dechallenge or</p> <p>7 rechallenge?</p> <p>8 (Witness reviewing document.)</p> <p>9 A. That's puzzling, I don't think there</p> <p>10 is, so I'm not sure where they got that</p> <p>11 information that they wrote in the paper.</p> <p>12 BY MR. PARKER:</p> <p>13 Q. So the record is clear, you're looking</p> <p>14 at the 2013 Mini-Sentinel report by the FDA that</p> <p>15 looks at celiac disease and its incident rate of</p> <p>16 ARBs including olmesartan and other drugs, I</p> <p>17 believe some ACE drugs?</p> <p>18 A. Yes. A variety of other</p> <p>19 antihypertensives.</p> <p>20 Q. So whatever these authors are</p> <p>21 referring to as the Mini-Sentinel is not the</p> <p>22 report you have in your hand?</p> <p>23 MR. SLATER: Objection.</p> <p>24 A. No, it's not.</p>	<p style="text-align: right;">Page 316</p> <p>1 they report an elevated, statistically</p> <p>2 significant elevated risk for developing celiac</p> <p>3 disease among olmesartan users compared to ARB</p> <p>4 users and ACE users.</p> <p>5 Am I reading that correctly?</p> <p>6 A. Yes, you are.</p> <p>7 Q. Doctor, have you read anything that</p> <p>8 would suggest that olmesartan causes celiac</p> <p>9 disease?</p> <p>10 A. No.</p> <p>11 Q. So a study, this study, that finds a</p> <p>12 four-fold increased risk for developing celiac</p> <p>13 disease, would that be considered a false</p> <p>14 positive finding by these investigators?</p> <p>15 A. The diagnosis of celiac disease is not</p> <p>16 the same as the diagnosis of</p> <p>17 olmesartan-associated enteropathy. So if you're</p> <p>18 asking if it's false to conclude that it is due</p> <p>19 to olmesartan, I would say the answer is yes.</p> <p>20 Q. If we turn to the first page of this</p> <p>21 report, on the lower right-hand portion of this</p> <p>22 page the authors -- and again, this study was</p> <p>23 published in 2015, is that right?</p> <p>24 A. Yes. 2016.</p>
<p style="text-align: right;">Page 315</p> <p>1 BY MR. PARKER:</p> <p>2 Q. Okay. Let's put that aside.</p> <p>3 And if you would, pull out the Basson</p> <p>4 paper.</p> <p>5 A. Is that an exhibit number?</p> <p>6 Q. I don't think -- let me check my</p> <p>7 notes. I don't think Mr. Slater had that</p> <p>8 marked. No, he didn't.</p> <p>9 A. I have it.</p> <p>10 Q. Okay. Let me see if I can find the</p> <p>11 reference.</p> <p>12 Doctor, if you would please turn to</p> <p>13 Page 3 of this paper. In the lower -- the</p> <p>14 paragraph beginning in the right-hand column at</p> <p>15 the bottom begins "Hospitalization with a</p> <p>16 discharge diagnosis"?</p> <p>17 A. Yes.</p> <p>18 Q. Just read to yourself along with me,</p> <p>19 but here they report the relative risks that</p> <p>20 they found for a discharge diagnosis of celiac</p> <p>21 disease comparing olmesartan versus other ACE</p> <p>22 and ARB drugs, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And for both of those comparisons,</p>	<p style="text-align: right;">Page 317</p> <p>1 Q. 2016. Excuse me.</p> <p>2 These authors write, "These reports,"</p> <p>3 referring to the publication of case reports</p> <p>4 that are discussed above, "These reports suggest</p> <p>5 that olmesartan may cause severe enteropathy,</p> <p>6 however the level of evidence of case reports in</p> <p>7 small series is limited."</p> <p>8 Do you agree with that statement?</p> <p>9 A. I do.</p> <p>10 MR. SLATER: Objection.</p> <p>11 BY MR. PARKER:</p> <p>12 Q. If we go to the next page of this</p> <p>13 paper, these investigators state in the first</p> <p>14 full paragraph on the left-hand column, "The</p> <p>15 association between olmesartan and enteropathy</p> <p>16 needs to be further investigated. The causality</p> <p>17 of the association remains uncertain and its</p> <p>18 magnitude has not been determined."</p> <p>19 Do you agree with that statement?</p> <p>20 A. I do.</p> <p>21 MR. SLATER: Objection.</p> <p>22 MR. PARKER: All right. I think we're</p> <p>23 done. Now we can go out.</p> <p>24 MR. SLATER: I've got a few follow-up</p>

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<p style="text-align: right;">Page 318</p> <p>1 questions.</p> <p>2 Okay. Do you want to do the camera</p> <p>3 thing again, Bruce?</p> <p>4 MR. PARKER: No, go ahead.</p> <p>5 MR. SLATER: Are you sure?</p> <p>6 MR. PARKER: Yep. They know who you</p> <p>7 are.</p> <p>8 FURTHER EXAMINATION</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Okay. Doctor, you were asked a</p> <p>11 question about the three top diagnoses for</p> <p>12 seronegative villous atrophy cases. One of them</p> <p>13 would be a medication-induced condition,</p> <p>14 correct?</p> <p>15 A. Yes.</p> <p>16 Q. And among the medication-induced</p> <p>17 conditions, the medical literature includes</p> <p>18 olmesartan as one of those medications that can</p> <p>19 cause this condition, right?</p> <p>20 A. I think in this you're talking about</p> <p>21 one specific paper, and they include olmesartan</p> <p>22 as one of their potential causes of</p> <p>23 medication-related villous atrophy. It's the</p> <p>24 DeGaetani paper. I presume that's what you're</p>	<p style="text-align: right;">Page 320</p> <p>1 it was before this information ever came out,</p> <p>2 right?</p> <p>3 A. Can I just look it up? I'm not sure</p> <p>4 that number of four is correct.</p> <p>5 Q. Sure. Two and two. You can look it</p> <p>6 up.</p> <p>7 (Witness reviewing document.)</p> <p>8 BY MR. SLATER:</p> <p>9 Q. It's on Page 735 under the Discussion,</p> <p>10 right-hand column, bottom half.</p> <p>11 A. Yes. Right. So yes, they discuss</p> <p>12 that. They don't actually report the data as</p> <p>13 data, but they do discuss it.</p> <p>14 Q. And in the Marthey study, the</p> <p>15 rechallenges, those occurred where the patients</p> <p>16 did not have any -- wouldn't have had any</p> <p>17 information regarding a potential connection to</p> <p>18 olmesartan, correct?</p> <p>19 A. Correct.</p> <p>20 Q. So there's no placebo effect in either</p> <p>21 of those studies, right?</p> <p>22 A. You would exclude the placebo effect</p> <p>23 related to specifically knowing about</p> <p>24 olmesartan, yes.</p>
<p style="text-align: right;">Page 319</p> <p>1 talking about.</p> <p>2 Q. I'm just following up on the questions</p> <p>3 you were asked.</p> <p>4 Now, you were asked questions about</p> <p>5 why you don't want uncontrolled rechallenges in</p> <p>6 your methodology, and I want to ask you about</p> <p>7 that.</p> <p>8 One thing you said is that you don't</p> <p>9 know what else is going on, and the second thing</p> <p>10 is the placebo effect, right?</p> <p>11 A. Right.</p> <p>12 Q. And you think the placebo effect is a</p> <p>13 very important factor that can impact on the</p> <p>14 validity of a rechallenge, I think that's what</p> <p>15 you've told us, because the patient knows</p> <p>16 they're back on the medication, so there can be</p> <p>17 this placebo effect. Do I understand that</p> <p>18 correctly?</p> <p>19 A. That's correct.</p> <p>20 Q. In Rubio-Tapia, those patients who had</p> <p>21 the anecdotal reports of going back on the drug</p> <p>22 and getting sick again, that was four patients,</p> <p>23 they didn't have any information that olmesartan</p> <p>24 was a potential cause of their condition because</p>	<p style="text-align: right;">Page 321</p> <p>1 Q. You were asked about celiac disease,</p> <p>2 and your suggestion -- well, rephrase.</p> <p>3 You were asked about whether or not</p> <p>4 you think it would be a good clinical paradigm</p> <p>5 to -- let me rephrase it.</p> <p>6 I think you just said, if I understood</p> <p>7 correctly, that you think it would be</p> <p>8 appropriate in the clinical treatment of</p> <p>9 patients who are suspected to have</p> <p>10 olmesartan-associated enteropathy to rechallenge</p> <p>11 them with olmesartan. Did I understand that</p> <p>12 correctly? You think that's actually something</p> <p>13 that doctors should do. Did I understand you to</p> <p>14 say that?</p> <p>15 A. I think you've got the exact opposite</p> <p>16 of what I said. I was explaining why it was</p> <p>17 important in celiac disease to be certain, and</p> <p>18 why uncertainty regarding cause was acceptable</p> <p>19 in these olmesartan cases, and why rechallenge</p> <p>20 didn't make any sense.</p> <p>21 Q. There is no peer-reviewed article that</p> <p>22 you can show me that suggests that a patient</p> <p>23 should be rechallenged with olmesartan when</p> <p>24 they've had a resolution of their symptoms after</p>

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<p style="text-align: right;">Page 322</p> <p>1 a dechallenge, there's not one article that 2 suggests that is an acceptable way to get a 3 further diagnosis of the patient, correct? 4 A. No, and I'm not suggesting that 5 either. 6 Q. Now, you were asked about the Marietta 7 article and the reference to the rechallenges 8 from the Mini-Sentinel study, and you couldn't 9 find anyplace where anybody said that that's 10 what was seen. Remember that? 11 A. Right. 12 Q. Do you have on the table the FDA Drug 13 Safety Communication that you were looking at 14 before? Actually we have it as document 22, we 15 might as well mark it if we haven't yet. 16 (Whereupon, Turner Exhibit Number 19, 17 FDA Drug Safety Communication, was 18 marked for identification.) 19 MR. SLATER: I'm trying to lighten 20 your load. Let's mark that as the next exhibit. 21 BY MR. SLATER: 22 Q. Okay. Doctor, do you see Exhibit 19 23 in front of you, the July 3, 2013 Drug Safety 24 Communication from the FDA?</p>	<p style="text-align: right;">Page 324</p> <p>1 very bottom they're talking about the 2 Mini-Sentinel, and then they continue to talk 3 about it over onto the third page. You see 4 that, right? 5 A. Right. But those data aren't in the 6 Mini-Sentinel. 7 Q. Okay. You were asked about the Basson 8 article, and you were asked about the fact that, 9 in part, they were looking for patients who were 10 hospitalized for celiac disease, right? 11 A. Right. 12 Q. Are you aware of the fact that the 13 published literature, some of the articles of 14 which you have relied on in your article, point 15 out that one of the issues with 16 olmesartan-associated enteropathy is that the 17 lack of knowledge in the medical community of 18 that caused numerous misdiagnoses of patients as 19 having celiac when they really had 20 olmesartan-associated enteropathy? Did you see 21 that in the literature? 22 A. So there's a lot of statements of fact 23 that I don't agree with at the beginning of 24 that.</p>
<p style="text-align: right;">Page 323</p> <p>1 A. Yes. 2 Q. Now, the FDA conducted the 3 Mini-Sentinel, so you would assume that they 4 would know what the results of that study were, 5 correct? 6 A. Correct. 7 Q. If you look over to the third page at 8 the very top, the "FDA identified 23 serious 9 cases in the FAERS database presenting as 10 late-onset diarrhea with significant weight loss 11 and, in some cases, with intestinal villous 12 atrophy on biopsy. All patients improved 13 clinically after discontinuation of olmesartan, 14 and a positive rechallenge was seen in 10 of the 15 cases." 16 Do you see that? 17 A. Yes. 18 Q. You'll accept that as a valid source 19 of information on the rechallenges, right? 20 A. Sure. What I said before was, I guess 21 I misspoke, I thought it was the Mini-Sentinel, 22 it's not, so this must be where I read it. I 23 suppose they should have referenced that. 24 Q. Well, you see on the prior page at the</p>	<p style="text-align: right;">Page 325</p> <p>1 Q. I'll ask it differently, then. If you 2 think it's unclear, I'll ask it differently. 3 Are you aware of articles in the 4 peer-reviewed literature that point out that due 5 to lack of information about 6 olmesartan-associated enteropathy, patients were 7 being diagnosed with celiac when they really 8 didn't have celiac, but they actually were 9 suffering from a condition due to olmesartan? 10 Have you seen that in the literature? 11 A. Again, you're concluding that a 12 disease due to olmesartan, and I can't agree 13 with that part of your question. 14 Q. But have you seen where the literature 15 says that? 16 A. I've seen where the literature says 17 there's an association, and the lack of 18 recognition of that association may have 19 resulted in patients being misdiagnosed as 20 having seronegative celiac disease. I've 21 also -- 22 MR. SLATER: I have no other 23 questions. 24 MR. PARKER: Okay. We are done.</p>

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<p style="text-align: right;">Page 326</p> <p>1 We'll read and sign.</p> <p>2 THE VIDEOGRAPHER: This concludes --</p> <p>3 MR. SLATER: Thank you very much,</p> <p>4 folks.</p> <p>5 Peter, thank you.</p> <p>6 MR. FOUNDAS: No problem.</p> <p>7 THE VIDEOGRAPHER: This concludes the</p> <p>8 February 16, 2017 deposition of Dr. Jerrold</p> <p>9 Turner. Going off the record. The time is</p> <p>10 5:10 p.m.</p> <p>11 (Whereupon, the deposition was</p> <p>12 concluded.)</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 328</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections.</p> <p>5 You should state the reason in the appropriate</p> <p>6 space on the errata sheet for any corrections</p> <p>7 that are made.</p> <p>8 After doing so, please sign the</p> <p>9 errata sheet and date it. It will be attached</p> <p>10 to your deposition.</p> <p>11 It is imperative that you return</p> <p>12 the original errata sheet to the deposing</p> <p>13 attorney within thirty (30) days of receipt of</p> <p>14 the deposition transcript by you. If you fail</p> <p>15 to do so, the deposition transcript may be</p> <p>16 deemed to be accurate and may be used in court.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 327</p> <p>1 COMMONWEALTH OF MASSACHUSETTS)</p> <p>2 SUFFOLK, SS.)</p> <p>3 I, MAUREEN O'CONNOR POLLARD, RMR, CLR,</p> <p>4 and Notary Public in and for the Commonwealth of</p> <p>5 Massachusetts, do certify that on the 16th day</p> <p>6 of February, 2017, at 9:14 o'clock, the person</p> <p>7 above-named was duly sworn to testify to the</p> <p>8 truth of their knowledge, and examined, and such</p> <p>9 examination reduced to typewriting under my</p> <p>10 direction, and is a true record of the testimony</p> <p>11 given by the witness. I further certify that I</p> <p>12 am neither attorney, related or employed by any</p> <p>13 of the parties to this action, and that I am not</p> <p>14 a relative or employee of any attorney employed</p> <p>15 by the parties hereto, or financially interested</p> <p>16 in the action.</p> <p>17 In witness whereof, I have hereunto</p> <p>18 set my hand this 20th day of February, 2017.</p> <p>19</p> <p>20</p> <p>21 MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC</p> <p>22 Realtime Systems Administrator</p> <p>23 CSR #149108</p> <p>24</p>	<p style="text-align: right;">Page 329</p> <p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>3 PAGE LINE CHANGE</p> <p>4 _____</p> <p>5 REASON: _____</p> <p>6 _____</p> <p>7 REASON: _____</p> <p>8 _____</p> <p>9 REASON: _____</p> <p>10 _____</p> <p>11 REASON: _____</p> <p>12 _____</p> <p>13 REASON: _____</p> <p>14 _____</p> <p>15 REASON: _____</p> <p>16 _____</p> <p>17 REASON: _____</p> <p>18 _____</p> <p>19 REASON: _____</p> <p>20 _____</p> <p>21 REASON: _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p>

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
 Hereby certify that I have read the foregoing
 pages, and that the same is a correct
 transcription of the answers given by me to the
 questions therein propounded, except for the
 corrections or changes in form or substance, if
 any, noted in the attached Errata Sheet.

 JERROLD R. TURNER, M.D., PH.D. DATE

Subscribed and sworn
 To before me this

_____ day of _____, 20 ____.

My commission expires: _____

 Notary Public

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LAWYER'S NOTES

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